

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion BP 50% w/v.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 50% w/v of Glucose EP

3 PHARMACEUTICAL FORM

Sterile Injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glucose 50% is hypertonic and provides a source of calories in a minimal volume of water. Glucose 50% is frequently used in both adults and children to restore blood glucose concentrations in the treatment of hypoglycaemia resulting from insulin excess or from other causes.

Glucose 50% may be used to provide temporary relief from the symptoms of cerebral oedema and from hypoglycaemic coma. Hyperosmotic Glucose with or without insulin may correct hyperkalaemia in renal failure and also some forms of hyponatraemia.

4.2 Posology and method of administration

Glucose 50% must be administered by the intravenous route; it must not be administered by subcutaneous or intramuscular route. Except in the emergency treatment of severe hypoglycaemia, Glucose 50% should be administered via a central vein after appropriate dilution. When used for the emergency treatment of hypoglycaemia, Glucose 50% may be administered slowly into a peripheral vein at a rate not greater than 3mls per minute.

Dosage of Glucose depends on the age, weight, clinical condition, the fluid, electrolyte and acid base balance of the patient. For the treatment of hypoglycaemia resulting from insulin excess or other causes in adults (including the elderly) and children, the usual dose is as follows:

20-50ml of Glucose 50% administered slowly intravenously. This represents 3mls per minute.

Repeated doses and supportive therapy may be required in some cases.

4.3 Contraindications

Glucose 50% is contraindicated in patients with the glucose – galactose malabsorption syndrome. Hypertonic Glucose solutions are contraindicated in patients with anuria or intraspinal or intracranial haemorrhage, or ischaemic stroke and in patients with delirium tremens if such patients are already dehydrated. Hypertonic Glucose solutions are also contraindicated in patients with diabetic coma or known allergy to corn or corn products.

4.4 Special warnings and precautions for use

Hypertonic solutions of Glucose should be administered via a large central vein to minimise damage at the site of injection (see section 4.2 Posology).

Glucose solutions should be used with caution in patients with overt or known sub-clinical diabetes mellitus, carbohydrate intolerance for any reason, severe under-nutrition, thiamine deficiency, hypophosphataemia, haemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.

Rapid administration of hypertonic glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome; patients should be observed for signs of mental confusion and loss of consciousness, especially those patients with chronic uraemia or carbohydrate intolerance.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored.

Changed in fluid balance, electrolyte concentrations and acid-base balance should be evaluated during prolonged therapy. Intravenous administration of Glucose may result in hypokalaemia, hypophosphataemia and hypomagnesaemia.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Intravenous glucose may result in foetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate. Infusions of glucose administered during Caesarean section and labour should not exceed 5-10g glucose/hour.

4.7 Effects on ability to drive and use machines

None known.

4.5 Undesirable effects

Metabolic and nutrition disorders:

Hyperglycaemia, hypokalaemia, hypophosphataemia, hypomagnesaemia, fluid and electrolyte imbalance.

Hyperglycaemia (possibly indicated by mental confusion or loss of consciousness) and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated hyperglycaemia can lead to dehydration, hyperosmolar coma and death.

The administration of glucose without adequate levels of thiamine may precipitate overt deficiency states e.g. Wernicke's encephalopathy. Sodium retention, oedema, pulmonary oedema and congestive heart failure may be induced in patients with severe under-nutrition.

Nervous system:

See Metabolic and nutrition disorders.

General and administration site disorders:

Pain at the injection site, vein irritation, venous thrombosis, phlebitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdose of Glucose 50% may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.

In the event of overdose of Glucose 50% it may be necessary to administer appropriate doses of insulin.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid
Water for Injections Ph. Eur.

6.2 Incompatibilities

Glucose solutions which do not contain electrolytes, should not be administered concomitantly with blood through the same infusion set, because of the possibilities of agglomeration.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at less than 25°C.

6.5 Nature and contents of container

20ml type I clear glass ampoules, packed in cardboard cartons to contain 10 ampoules x 20ml.

50ml type II clear glass vials, packed in cardboard cartons to contain 10 or 25 vials x 50ml.

6.6 Special precautions for disposal

Use as directed by the physician.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 01502/0075

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/02/2011

10 DATE OF REVISION OF THE TEXT

23/10/2020